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EXAMINER	
MARVICH, MARIA	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YUQIAO SHEN, JULIE NYE and TERRY HERMISTON

Appeal 2009-014665
Application 10/669,768
Technology Center 1600

Decided: March 22, 2010

Before ERIC GRIMES, DONALD E. ADAMS, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating cancer with a recombinant virus, which the Examiner has rejected as nonenabled. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 11, 12, 24, 28, 33, 39, and 40 are on appeal. Claim 11 is representative and reads as follows:

11. A method of treating a cancer, characterized by neoplastic cells that substantially lack p53 function, in a patient in need of the treatment, comprising

administering chemotherapy to said patient,

administering to said patient a dose of a recombinant adenovirus, said recombinant adenovirus comprising a mutation in the E1B-55K gene, said gene encoding a mutated E1B-55K protein comprising a single amino acid substitution mutation, said single amino acid substitution mutation reducing the ability of said mutated E1B-55K protein to bind to the tumor suppressor p53 when compared to the ability of wild-type E1B-55K protein to bind to the tumor suppressor p53 and said recombinant adenovirus has the further property of retaining late viral function, and

allowing sufficient time for said recombinant adenovirus to infect neoplastic cells of said cancer.

I.

Issue

The Examiner has rejected claims 11, 12, 24, 28, 33, 39, and 40 under 35 U.S.C. § 112, first paragraph, on the basis that "the specification, while being enabling for treatment of cancer characterized by p53 loss or deficiency by direct administration [of] Onyx 051 or 053 (comprises a single amino acid substitution in amino acid 240 or 260), does not reasonably provide enablement for any other embodiment" (Ans. 3). The Examiner finds that the "invention is unpredictable for treatment of cancer in humans given the broad recitation of a genus of adenovirus for delivery to p53 lacking neoplastic cells wherein the adenovirus ha[s] reduced binding to p53" (*id.* at 5), and concludes that "[g]iven the large breadth of the claims in light of the unpredictable nature of cancer treatments and the unpredictable nature of developing oncolytic virus, the invention requires undue experimentation" (*id.* at 7).

Appellants contend that the Specification provides ample guidance to enable skilled workers to make recombinant viruses having the properties recited in the claims (Appeal Br. 14-16) and that the present application is a divisional of a patent containing claims to the same viruses (*id.* at 17-18). Appellants contend that the Examiner has acknowledged that the claimed method is effective for treating p53(-) tumors (*id.* at 12) and that undue experimentation would not be required to practice the full scope of the claims (*id.* at 12-14).

The issue presented is: Does the evidence of record support the Examiner's conclusion that undue experimentation would be required to use recombinant adenoviruses having the properties recited in claim 11 to treat cancer?

Findings of Fact

The present application is "a divisional of U.S. Patent Application Serial No. 09/918,696, filed July 30, 2001, now U.S. Patent No. 6,635,244" (Specification 1, as amended Sept. 21, 2006). Claim 1 of the '244 patent reads as follows:

> A recombinant adenovirus comprising a mutation in the E1B-55K gene, said gene encoding a mutated E1B-55K protein comprising a single amino acid mutation, said single amino acid mutation reducing the ability of said E1B-55K mutated protein to bind to the tumor suppressor p53 when compared to the wild-type E1B-55K protein and said adenovirus has the further property of retaining late viral function.

('244 patent, col. 38, ll. 59-67.)

The Examiner has concluded that "the specification . . . [is] enabling for treatment of cancer characterized by p53 loss or deficiency by direct administration [of] Onyx 051 or 053" (Ans. 3).

Onyx 051 and Onyx 053 are recombinant adenoviruses having the following mutations in the E1B-55K gene: arginine-to-alanine at amino acid 240 (Onyx 051) or histidine-to-alanine at amino acid 260 (Onyx 053) (Spec. 20: 6-7). Onyx 051 and Onyx 053 do not bind p53 (*id.* at 20: 9-10; 20: 34-35). The Specification discloses that "Onyx 051 (mutant R240A) and Onyx 053 (H260A) maintain the normal late functions of the wild-type protein" (*id.* at 23: 16-17).

Principles of Law

The claims of a U.S. Patent are presumed to be valid. 35 U.S.C. § 282.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

Analysis

The present application is a divisional of the '244 patent, and therefore shares the same specification as that of the '244 patent. The Office has already determined that that shared specification is enabling for the recombinant adenoviruses recited in the present claims. The Examiner has

conceded that the claimed method of treating cancer can be practiced, without undue experimentation, using two viruses having the properties recited in the claims. All of the methods encompassed by the claims require using viruses having those same properties. The Examiner has not provided an adequate basis for concluding that practicing the claimed method, using other recombinant adenoviruses having the same properties as those the Examiner has deemed enabled, would require anything more than routine experimentation.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that undue experimentation would be required to use recombinant adenoviruses having the properties recited in claim 11 to treat cancer. Claim 33 is the only other independent claim on appeal and requires using recombinant adenoviruses having the same properties.

SUMMARY

We reverse the rejection of claims 11, 12, 24, 28, 33, 39, and 40 for nonenablement.

REVERSED

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